Puget Sound
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and Program

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July 19, 1999

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

FDA Docket No. 98D-1171

To Whom It May Concern:

I am writing regarding the draft document "Guidance for Industry For Platelet Testing And Evaluation Of Platelet Substitute Products." Under Section III-C, first paragraph, I have comments regarding the relevance of the bleeding time test. Although it may be "true" that the bleeding time test cannot necessarily be used to predict post-surgical bleeding, there are numerous studies suggesting that there is a direct relationship between bleeding time and platelet count, and that the bleeding time does adequately measure the hemostatic efficacy of platelets following transfusion.[1-4] Similar data has been shown in a rabbit bleeding time model where the post-transfusion platelet increments correlate with reduction in bleeding time.[5] Therefore, the statement that bleeding time measurements do not reflect the hemostatic efficacy of platelet transfusions is not correct. Besides the stool blood loss measurements referred to later in Section III-D, the bleeding time test and the stool blood loss measurements are the only available methods available to document the hemostatic efficacy of either standard platelets or platelet substitutes. Furthermore, we have recent evidence evaluating UV-A and psoralen treated platelet transfusions that, again, demonstrate a relationship between post-transfusion platelet count and bleeding time. This information may be available to you through Dr. Vostal at the FDA.

Sincerely,

Sherrill J. Slichter, M.D.
Director, Division of Research and Education
Puget Sound Blood Center

Professor of Medicine, Hematology / Medicine
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SJS/vkk

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[1]Harker LA, Slichter SJ. The bleeding time as a screening test for evaluating platelet function. New Engl J Med 287:155, 1972.

[2]Slichter SJ, Harker LA. Preparation and storage of platelet concentrates. II. Storage variables influencing platelet viability and function. Br J Haematol 34:403, 1976.

[3]Scott EP, Slichter SJ. Viability and function of platelet concentrates stored in CPD-adenine (CPDA-1). Transfusion 20:489, 1980.

[4]Kahn RA, Merryman HT. Storage of platelet concentrates. Transfusion 16:13, 1976.

[5]Blajchman MA, Lee, DH. The thrombocytopenic rabbit bleeding time model to evaluate the *in vivo* hemostatic efficacy of platelets and platelet substitutes. Transfus Med Rev 12:175, 1998.

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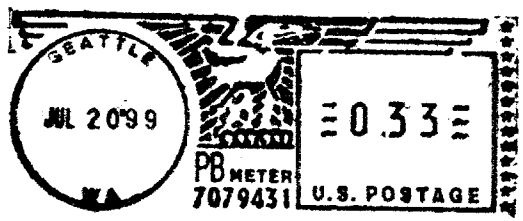

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